AUG 2 3 2001

SECTION E - 510(k) SUMMARY

Submitter's Name and Address:

Medtronic Physio-Control Corp.
11811 Willows Road Northeast
P.O. Box 97006
Redmond, WA 98073

Contact Person:

Sherri L. Pocock
(425) 867-4332

Date Summary Prepared:

March 7, 2001

Device:

Medtronic Physio-Control LIFEPAK® 12 Defibrillator/Monitor System

(Labeling change: addition of information regarding the use of the Medtronic Physio-Control biphasic waveform in cardioversion of atrial arrhythmias and for direct defibrillation of the heart during open chest surgical procedures)

Classification:

Low-Energy DC - Defibrillator: Class II (21 CFR 870.5300)

Automatic External Defibrillators have been considered Class III devices by FDA.

Cardiac Monitors (including Cardiotachometers and Rate Alarms): Class II (21 CFR 870.2300)

Substantial Equivalence:

This LIFEPAK 12 defibrillator/monitor system is substantially equivalent to the currently marketed versions of the device:

- Original (monophasic) LIFEPAK 12 defibrillator/monitor system K973486, cleared 1/9/98
- Noninvasive blood pressure and CO2 monitor options K990338, cleared 9/1/99
- Biphasic defibrillator waveform option K991910, cleared 9/3/99
- Invasive pressures option K002445, cleared 1/31/01

Description:

The LIFEPAK® 12 defibrillator/monitor series is a complete acute cardiac response system, which consists of a battery or auxiliary powered defibrillator (manual or automated); pacemaker; 3-lead, 5-lead and interpretive 12-lead ECG monitor; pulse oximeter; noninvasive blood pressure monitor; end-tidal C02 monitor; and invasive pressures monitor. Data can be transmitted by landline or cell phone to computer, fax, printer, or an ECG storage system.

The users of the device are Advanced Life Support and Basic Life Support providers in a variety of hospital and pre-hospital settings. The device is used in various areas of the hospital such as critical areas (emergency departments, critical care, operating room, etc.) and general duty floors (e.g., medical/surgical). The device is also used for in and out of hospital transport (air and ground ambulance, in hospital transport, etc.).

The subject of this 510(k) premarket notification is a labeling change. We are adding information related to the effectiveness of the Medtronic Physio-Control biphasic defibrillation waveform for cardioversion of atrial arrhythmias and for internal paddles defibrillation. No other feature or function of the device is affected. There is no change to the device itself.

Intended Use:

Defibrillation is a means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. A direct current defibrillator applies a brief, intense pulse of electricity to the heart muscle. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

The biphasic waveform has been clinically studied on adults; it has not been studied on pediatric patients.

Technological characteristics of new and predicate devices:

The features and functions of the new LIFEPAK 12 are the same as those of the currently marketed LIFEPAK 12 system.

Summary of Performance Information:

Atrial Fibrillation:

We conducted a prospective, randomized, multicenter clinical trial to compare the efficacy and post-procedure local pain associated with elective cardioversion of Atrial Fibrillation (AF) with the Medtronic Physio-Control biphasic truncated exponential (BTE) and conventional monophasic damped sine waveform shocks. We constructed dose response curves for these waveforms to guide clinicians in selection of energy levels for cardioversion of AF with these BTE shocks.

This study showed the Medtronic Physio-Control BTE shocks provide higher efficacy for cardioversion of atrial fibrillation, require fewer shocks and much less electrical current and energy to cardiovert atrial fibrillation and result in less post-procedure local pain than conventional monophasic damped sine shocks.

Internal Paddles Defibrillation:

We compared the efficacy of the Medtronic Physio-Control BTE waveform to the conventional monophasic damped sine waveform in a prospective, randomized multicenter study of patients undergoing direct, open chest defibrillation. The study showed

that these BTE shocks have higher defibrillation efficacy, and require fewer shocks, less threshold energy and less total energy than conventional monophasic damped sine shocks.

This information demonstrates that the LIFEPAK 12 is substantially equivalent to the predicate devices with respect to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2001

Mr. Michael D. Willingham
Medtronic Physio-Control Corp.
11811 Willows Road NE
Redmond, WA 98073-9706

Re: K010918
LIFEPAK® 12 Biphasic Defibrillator/Monitor System
Regulation Number: 21 CFR 870.1025
Regulatory Class: III (three)
Product Code: 74 MKJ, LDD, MWI
Dated: July 6, 2001
Received: July 9, 2001

Dear Mr. Willingham:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

P1/2

SECTION D - STATEMENT OF INDICATIONS FOR USE

Ver/ 3 - 4/24/96

Applicant: Medtronic Physio-Control Corp.

510(k) Number (if known): 510(k) Number Not yet assigned K010918

Device Name: LIFEPAK 12 defibrillator/monitor system

Indications For Use:

Defibrillation is a means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. A direct current defibrillator applies a brief, intense pulse of electricity to the heart muscle. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

The biphasic waveform has only been clinically studied on adults; it has not been studied on pediatric patients.

The Automated External Defibrillation mode is for use on patients in cardiopulmonary arrest. It is not intended for use on patients less than eight years old.

Noninvasive pacing is indicated for patients with symptomatic bradycardia or asystole.

12 lead electrocardiography is useful in the early detection and prompt treatment of patients with acute myocardial infarction. Documentation of transient or intermittent arrhythmias and other electrophysiologic events that occur in the prehospital setting can assist in diagnosis and treatment decisions in the emergency department.

Pulse oximetry is used to check the saturation of oxygen in arterial blood. It is indicated for use in any patient who is at risk of developing hypoxemia.

Noninvasive blood pressure monitoring is intended for detection in trends of hypertension or hypotension. These include patient conditions indicated by abnormalities in various physiologic parameters such as shock, evaluation of perfusion during dysrhythmias, major fluid shifts, evaluation of response to fluid therapy, and titration of vasoactive and cardiotronic drugs. Noninvasive blood pressure monitoring may be useful during ECG monitoring or for post-defibrillation recovery analysis.

End-Tidal CO2 monitoring is intended to be used for detection of trends in the level of expired CO2. It is used for monitoring breathing efficacy in acute cardiopulmonary care, for example, to determine if adequate compressions are being performed during CPR or to rapidly detect whether an endotracheal tube has been placed successfully.

Invasive Pressures Monitoring

The LIFEPAK 12 IP monitor is intended for use in monitoring arterial, venous, intracranial and other physiologic pressures using an invasive catheter system with a compatible transducer.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Prescription Use ✓
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K040918